DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 30, 2015

ACON LABORATORIES, INC.
QIYI XIE
SR.STAFF REGULATORY AFFAIRS/CLINICAL AFFAIRS
10125 MESA RIM ROAD
SAN DIEGO CA 92121

Re: K150330
Trade/Device Name: Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine)
Regulation Number: 21 CFR 862.1645
Regulation Name: Urinary protein or albumin (nonquantitative) test system
Regulatory Class: II
Product Code: JIR, JFY
Dated: February 7, 2015
Received: February 10, 2015

Dear Qiyi Xie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)
K150330

Device Name
Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine)

Indications for Use (Describe)
The Mission Urinalysis Reagent strips (Microalbumin/Creatinine) are intended for the semi quantitative measurement of albumin and creatinine in urine samples using the Mission U120 Urine Analyzer. These measurements are used to assist diagnosis for kidney function. It is intended for professional use only at point-of-care locations.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Assigned 510(k) number is: k150330

Submitter's Identification:

ACON Laboratories, Inc.

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Tel.: 858-875-8019

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Date Prepared: February 7, 2015

Contact Person:

Qiyi Xie

Senior Staff, Clinical & Regulatory Affairs

Email: qxie@aconlabs.com

Proprietary Name of the Device:

Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine)

Common Name:

Urinalysis Reagent Strips

Classification Name:

21 CFR 862.1645 Urinary protein or albumin (nonquantitative) test system

21 CFR 862.1225 Creatinine test system

Predicate Device:

CLINITEK Microalbumin Reagent Strips
BAYER CORPORATION
1884 Miles Avenue, P.O. Box 70
Elkhart, IN 46515
510(k) Number: K972706

Device Name: Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine)

Proprietary Name	Classification	Product	Description	Common Name
Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine)	862.1645 Class I	JIR	Urinary Protein or Albumin (nonquantitative) test system	Urinalysis Reagent Strips
	862.1225 Class II	JFY	Creatininine test system	

Device Description:

The Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine) are firm plastic strips that contain two reagent areas to test for Microalbumin (low concentration of albumin) and creatinine in urine. Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine) can be read by the Mission® U120 Urine Analyzer.

Instrument Reading

The Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine) are dipped into a urine specimen and "read" instrumentally by the Mission® U120 Urine Analyzer, (K070929). The urine analyzer is a reflectance photometer that analyzes the intensity and color of light reflected from the reagent areas of a urinalysis reagent strip. In addition to providing an albumin and a creatinine result, an albumin-to-creatinine ratio can also be determined. Semi-quantitative results are available within one minute.

Intended Use:

The Mission Urinalysis Reagent strips (Microalbumin/Creatinine) are intended for the semi quantitative measurement of albumin and creatinine in urine samples using the Mission U120 Urine Analyzer. These measurements are used to assist diagnosis for kidney function. It is intended for professional use only at point-of-care locations.

Tests Principles:

Albumin: The basis for the test is a high affinity sulfonephthalein dye, using the dye binding method to produce any blue color if albumin is present at a constant pH. Results range in color from pale green to aqua blue. In the presence of diluted urine, the pad for the Albumin reading will turn white. This indicates an albumin level ≤ 10 mg/L. Normally, albumin is present in urine at concentrations < 20 mg/L. Results of 20-200 mg/L may indicate micralbuminuria. It is associated with early-stage kidney disease when a small amount of Albumin, also called Microalbumin is consistently present in urine. Clinical albuminuria is indicated by results of >200 mg/L. These levels can be predictive of albumin excretion rates of 30-300 mg/24hours and >300 mg/24hours, respectively. Exercise, acute illness and fever, and urinary tract infections may temporarily elevate urinary albumin excretions.

Creatinine: The peroxidase-like activity of a copper creatinine complex catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'- tetramethylbenzidine to produce a resulting color range from orange through green to blue. Creatinine concentrations of 10-300 mg/dL are normally present in urine.

Albumin-to-Creatinine Ratio: It is also called Microalbumin-to-Creatinine ratio test available to assess microalbuminuria. Albumin is normally present in urine at concentrations of <30 mg albumin/g creatinine. Microalbuminuria is indicated at a ratio result of 30-300 mg/g (Abnormal) and clinical albuminuria at a ratio of >300 mg/g (High Abnormal).

Substantial Equivalence:

The Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine) are substantially equivalent to the CLINITEK Microalbumin Reagent Strips (K972706)

Characteristic of the Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine) are compared with the CLINITEK Microalbumin Reagent Strips (K972706) for instrument reading in the following table:

Area of Comparison	Mission® Urinalysis Reagent Strips (Microalbumin/Creatinine)	CLINITEK Microalbumin Reagent Strips (K972706)
Indications for Use	The Mission Urinalysis Reagent strips (Microalbumin/Creatinine) are intended for the semi quantitative measurement of albumin and creatinine in urine samples using the Mission U120 Urine Analyzer. These measurements are used to assist diagnosis for kidney function. It is intended for professional use only at point-of-care locations. The strips are read instrumentally by the Mission® U120 urine analyzer.	Clinitek Microalbumin Reagent Strips are for screening urine specimens to test for small amounts of albumin in urine (microalbuminuria), creatinine in urine, and also determine the albumin-to-creatinine ratio in urine. Clinitek Microalbumin Reagent Strips can be used for screening urine specimens for microalbuminuria as an aid in the detection of patients at risk for developing kidney damage. The strips are read instrumentally using the Clinitek Status Analyzer (K031947).
Intended Use	Professional use in point-of-care urine testing	Same
Target Population	Patients of physicians, hospitals, and clinics	Same
Intended Specimen	Urine	Same
Material Provided	Plastic strips affixed with two separate reagent areas.	Same
Test Time	1 Minute	Same
Albumin Methodology	This test is based on dye binding using a high affinity	Same

	sulfonephthalein dye. At a constant pH, the development of any blue color is due to the presence of albumin. The resulting color ranges from pale green to aqua blue	
Creatinine Methodology	This test is based on the peroxidase-like activity of a copper creatinine complex that catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange through green to blue	Same
Detection	Detects albumin between 10-150 mg/L Detects creatinine between 10-300 mg/dL (0.9 -26.5 mmol/L)	Same
Differences		
Storage	2 to 30ºC	15 to 30ºC

Discussion of Clinical Accuracy Tests Performed:

A total of 390 urine specimens were randomly collected at three clinical sites from patients. Each specimen was tested by Mission U120 Urine Analyzer with Mission Urinalysis Microalbumin/Creatinine Reagent strip and predicate device. The results are summarized in the table below:

A:C		Predicate Device			
		<30	30-300	>300	Total
Mission Urinalysis Reagent Strips	<30	164	12	0	176
	30-300	15	112	11	138
	>300	0	4	72	76

	Total	179	128	83	390
Agreement at same block		91.6%	87.5%	86.7%	
Agreement within ±1 block		100%	100%	100%	
Positive Agreement			90.6%	100%	
Negative Agreement		91.6%			
Agreement within same block			89.2%		
Agreement within ±1 block			100%		

The agreement of A:C ratios of positives and negatives at cutoff of <30 mg/g were 94.3% and 91.6%, respectively. Of the 211 A:C positive results, 5.7% (12/211) were negative. Of the 179 assay A:C ratio negative results, 8.4% (15/179) were positive. In summary, the overall exact agreement between Mission Urinalysis Strips Microalbumin/Creatinine) and Clinitek Microalbumin 2 Reagents strips for positive albumin results is 89.2%, and the overall agreement for ±1 block is 100%.

Discussion of Performance Tests Performed:

The performance characteristics of the Urinalysis Reagent Strips (Urine) have been determined in both laboratory and clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy and precision. Generally, this test has been developed to be specific for the parameters to be measured with the exceptions of the interferences listed.

Precision: The reproducibility of the Mission U120 Urine Analyzer to read Mission® Urinalysis Reagent Strips (Microalbumin/ Creatinine) was evaluated by within run precision and between run precision studies at three POL sites using Control Solutions Level 1 (Neg.), Level 2 (Low) and Level 3 (High). Within run precision study: Each level of the control solution was tested in 20 replicates in one day at each of POL sites. Between run precision study: Each control was tested once at each run, 2 runs per day for 20 days, 3 operators from each site participated the study. The results of within-run and between-run precision studies showed that the agreements with each target concentration were over 99% for the U120 Ultra.

Interference Study: Three levels of urine controls were spiked with the possible interfering substances one at a time to two concentrations following EP7-A2: Level 2 (common pathological value) and level 1 (5 times lower than level 2). Each sample was tested in triplicates. Results are summarized in the table below:

Substances	Conc. Tested	Interference on the Testing Result	
		Result of Albumin	Result of Creatinine
Human IgG	25 mg/dL	+1	N/A
Sodium Bicarbonate	1500 mg/dL	+2	N/A
Potassium Chloride	1500 mg/dL	-2	N/A
Hemoglobin	10 mg/dL	+1	+1
Blood	0.05%	+2	+1

Conclusion:

The laboratory testing results and clinical studies demonstrate that the Mission® Urinalysis Reagent Strips (Microalbumin/ Creatinine) read by Mission® U120 Urine Analyzer is safe, effective and easy-to-use and such is substantially equivalent to the Clinitek Microalbumin Reagent Strips (K972706) read by Clinitek Status Analyzer (K031947), currently sold on the U.S. market for professional use at point-of-care locations.